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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,994	01/17/2007	Seiichiro Kawashima	295483US0PCT	5781

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EXAMINER	
BARKER, MICHAEL P	
ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/594,994	KAWASHIMA ET AL.	
	Examiner	Art Unit	
	MICHAEL BARKER	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 6* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/06;12/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3 are provisionally rejected under obviousness-type double patenting. Claims 5 and 6 are also rejected under 35 USC 112, first paragraph.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 12/29/2006 and 12/8/2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered.

Claim Objections

Claims 2-6 are objected to as they depend from a rejected base claim (claim 1).

Claims 5 and 6 are objected to under 37 CFR 1.75(c) as being in improper form because each are improper multiple dependent claims. See MPEP § 608.01(n).

Applicant is advised to amend these claims. Suggested language to overcome this objection would include, ". . .at least one compound as claimed in any one of claims 1 to 4 as effective component."

Claim Rejections

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5, and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 15 of copending Application No. 11/847,593.

Specifically, the '593 Application discloses 2-(2-difluoromethyl-6-ethoxybenzimidazol-1-yl)-4,6-dimorpholino-1,3,5-triazine and 2-(2-difluoromethyl-4-methoxybenzimidazol- 1-yl)-4-(2,6-dimethylmorpholino)-6- morpholinopyrimidine at claim 6 and the same two compounds at claim 15.

2-(2-difluoromethyl-6-ethoxybenzimidazol-1-yl)-4,6-dimorpholino-1,3,5-triazine reads on the genus of compounds disclosed in present claim 1, as well as claims 5 and 6 each of which depend from claim 1.

2-(2-difluoromethyl-4-methoxybenzimidazol- 1-yl)-4-(2,6-dimethylmorpholino)-6-morpholinopyrimidine reads on the genus of compounds disclosed in present claim 1, as well as the species identified in claim 3, and claims 5 and 6.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 USC 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling the treatment of human colon cancer, does not reasonably provide enablement for treatment of every malignant tumor. The specification does not enable the skilled artisan to make and use the invention commensurate in scope with these claims.

Undue experimentation is a conclusion reached by weighing the factual considerations set forth by the Federal Circuit in *In re Wands*. 858 F.2d 731, 737; 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include:

1) Breadth of the claims;
2) Nature of the invention;
3) State of the prior art;
4) Level of one of ordinary skill in the art;
5) Level of predictability in the art;
6) Amount of direction provided by the inventor
7) Existence of working examples; and
8) Quantity of experimentation need to make/use the invention based on content of disclosure.

Claim 5 is drawn to, “An anti-malignant-tumor agent containing at least one compound as claimed in claims 1 to 4 as effective component.” Claim 5 is interpreted

as any compound specified in one of claims 1 through 4 which acts as an agent against any malignant tumor.

Similarly, claim 6 is drawn to "A pharmaceutical composition including at least one compound as claimed in claims 1 to 4 as anti-malignant-tumor active component together with pharmaceutically acceptable diluent or carrier." Claim 6 is interpreted as a pharmaceutical composition which contains any compound specified in one of claims 1 through 4 which acts as an agent against any malignant tumor.

The state of the prior art, level of ordinary skill, and level of predictability are not such that the skilled artisan could make and use the invention as recited in claims 5 and 6. Applicant provided experimental data which is adequate to conclude that the compounds claimed are capable of treating a rat with human colon cancer *in vivo*, no data is shown pertaining to any other cancers *in vivo*.

At pp. 19 and 20 of the specification, Applicant states:

> The compounds of the present invention were also effective in vitro tests using human colon cancer cells, human lung cancer cells, human breast cancer cells or human prostata cancer cells and therefore positively expected is application of the compounds according to the present invention to treatment of various human solid cancers.

However, cancer treatment is not so predictable. The skilled artisan could not expect that the in vitro tests using cancer cells other than human colon cancer would correlate to in vivo tests. The value of preclinical cancer models in predicting clinical utility is discussed at length in Voskoglou-Nomikos, et al., *Clin. Can. Res*. vol. 9, pp.

4227-4239 (2003). Essentially, certain preclinical cancer models may be predictive of clinical utility, while others may not. Predictability varies based on the type of preclinical model used and types of cancers tested. Furthermore, the state of the art is not such that any one compound is capable of treating all known malignant tumors.

Accordingly, undue experimentation would be necessary in order to determine how to make and use the claimed compounds as suggested in claims 5 and 6, namely, for treatment of any malignant tumor. Applicant is advised that narrowing the scope of these claims to human colon cancer, as suggested in the specification, would overcome this rejection.

For instance, claim 5 may be rephrased to recite, "An agent containing at least one compound as claimed in [any one of] claims 1 to 4, effective to treat human colon cancer." Likewise, claim 6 may be rephrased in a similar manner.

Conclusion

Any inquiry concerning this Office Action should be directed to Michael P. Barker at (571)272-0303, normally reachable from Monday through Friday, 8 am to 5 pm. If attempts to reach the Examiner are unsuccessful, please try the Examiner's supervisor, Joseph K. McKane at (571)272-0699.

Information regarding the status of an application may be obtained from the private or public PAIR system. Information about PAIR may be found at http://pair-direct.uspto.gov or 866.217.9197.

/MICHAEL BARKER/

Examiner, Art Unit 1626

/Kamal A Saeed/

Primary Examiner, Art Unit 1626